REMARKS

Claims 153 and 168 have been amended. New claims 183-204 have been added. Upon entry of this amendment, claims 153-204 will be pending in the present application.

The subject matter of claims 183-204 is within the scope of the subject matter of claims 153-162, 166-177 and 181-182, as they existed prior to this amendment. The Applicant has carved out a portion of the subject matter of claim 153, re-presented the carved out subject matter as new claim 183, adding in a limitation corresponding to the limitation of claim 154, and further limiting new claim 183 to require a component having a molecular weight less than 1,000. Basis for this amendment can be found in Example 2 of the application as originally filed. Dependent claims 184-193 correspond to dependent claims 155-162 and 166-167, except that they depend from new claim 183.

Similarly, Applicant has carved out a portion of claim 168, re-presented the carved out subject matter as new claim 194, adding in a limitation corresponding to the limitation of claim 169, and further limiting new claim 194 to require a component having a molecular weight less than 1,000. Basis for this amendment can be found in Example 2 of the application as originally filed. Dependent claims 195-204 correspond to dependent claims 170-177 and 181-182, except that they depend from new claim 194. Favorable consideration and entry of these narrowing amendments to the claimed subject matter is requested.

Claims 153-182 have been rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. In particular, the Examiner states that specification does not describe a method for preventing the appearance of a symptom after infection, as presently claimed.

Applicant has amended claims 153 and 168 to remove the recitation "preventing the appearance of symptoms," reciting instead "providing a remedial effect" for a disease infection. Support for this amendment may be found, for example, on page 11, lines 10-14, and page 23, lines 7-24 of the specification as originally filed. Thus, it is considered that the proposed amendment removes the basis for the Examiner's rejection. Accordingly, for these reasons, favorable consideration, entry of the amendment to claims 153 and 168, and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is requested.

Claims 153-182 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. In particular, the Examiner states that the terms "appearance of a symptom after infection" in claims 153 and 168 are vague and indefinite, specifically for failing to set forth what is included or excluded from an appearance of a symptom after infection.

Applicant has amended claims 153 and 168 as described above to deleted the terminology "appearance of a symptom after infection." Thus, it is considered that the proposed amendment removes the basis for the Examiner's rejection. Accordingly, for these reasons, favorable consideration, entry of the amendment to claims 153 and 168, and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph is requested.

Claims 153-158, 160, 163-173, 175, 178-182 have been rejected under 35 U.S.C. §102(a) as being anticipated by European published patent application no. EP 0 943 343 A1 (Kawai et al.). Specifically, the Examiner stated that,

> Applicant argues that Kawai does not teach the humans or animals are infected with bacteria, viruses or fungus or that the method prevents symptoms of infection from appearing.
> However, these arguments fail to persuade because the claims do not require the human or animal to be infected, or that the subject be in need of symptom prevention or disease remedying. The claims merely require that a human or animal is administered the sugar cane derived extract. While the reference does not teach the method steps can prevent appearance of symptoms after infection, or remedy an infectious disease, the steps are the same, and therefore must inherently prevent appearance of symptoms after infection.

See pages 5 and 6 of the April 16, 2004 Final Office Action. This rejection, at least insofar as it applies to claims 153 and 168, as amended, is respectfully traversed and reconsideration is requested for the reasons that follow.

Applicants have amended claims 153 and 168 to clearly recite a method for providing remedial effect for a disease caused by an infection in humans or animals by providing an human or animal after infection with the disease, an effective amount of the extract to provide a remedial effect for said disease and that infection is a bacterial infection (claim 153) or a fungal infection (claim 168). Thus, it is considered that the proposed amendment removes the basis for the Examiner's rejection quoted above.

Kawai et al. teaches methods of administration of sugar cane extracts to humans and dogs in Examples 4-5 of Kawai et al. for the purpose of preventing or reducing odor. In each case, the compositions were orally administered to humans and dogs.

The present invention, as claimed in amended claims 153 and 168, is clearly novel over Kawai et al. since amended claims 153 and 168 now require administration of a sugar cane extract to a human or animal to provide a remedial effect to a human or animal infected with a bacterial infection (or as claimed in 168, a fungal infection). Kawai et al. contains no teaching or suggestion to administer a sugar cane extract to an infected human or animal to provide a remedial effect, nor would a skilled person be led to administer a sugar cane extract to an infected or diseased human or animal by the teachings of Kawai et al., since Kawai et al. does not teach or suggest any beneficial effect that would be obtained which is related to the treatment of a disease caused by an infection.

The Examiner further states:

> Although Kawai does not teach the method for preventing appearance of symptoms from infection or remedying infectious disease, the method steps are the same. Moreover, by practicing Kawai, one would inherently be preventing appearance of symptoms after infection. In addition, although Kawai does not specifically teach the extract absorbs light at a wavelength of 420 nm, the methods of obtaining the extracts are the same. As such it would appear that the extract of Kawai would also intrinsically absorb light at the same wavelength. It is noted that if the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference produce was made by a different process. When the prior art discloses a product which reasonably appears identical with or slightly different from the claimed product-by process rejections under 35 U.S.C. 102 and/or 35 U.S.C. 103 are proper.

See pages 5 and 6 of the April 16, 2004 Final Office Action.

A similar situation arose in the case of In re Marshall, 578 F.2d 301, 198 USPQ 344 (CCPA 1978) (copy enclosed). In this case, the prior art disclosed the use of oxethazaine to inhibit the release of the acid-stimulating hormone, gastrin, in order to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome. The Boards of Appeal had taken the position that this reference inherently anticipated the applicant's claims directed to a method for the use of oxethazaine to inhibit release of the pancreatic secretory hormones, secretin and pancreozymin, in order to control weight on the basis that a person taking oxethazaine to inhibit the release of gastrin would inherently inhibit release of secretin and pancreozymin.

The Court of Customs and Patent Appeals, in the decision of In re Marshall, cited infra, disagreed with this reasoning and reversed the rejection of the Board of Appeals stating that if anyone ever lost weight by following the teachings of the prior art reference to take oxethazaine

to inhibit release of gastrin, it was an unrecognized accident. The court then said that, "An accidental or unwitting duplication of an invention cannot constitute an anticipation." The same reasoning applies to the anticipation rejection over Kawai et al. in the present case.

More specifically, the Examiner has taken the position that since Kawai et al. discloses methods of administration of sugar cane extracts to humans and dogs for the purpose of preventing or reducing odor, a person following the teachings of Kawai et al. would inherently provide a remedial effect for a disease when the sugar cane extract of Kawai et al. were administered to a human or animal that had already been infected by the infection. However, as in In re Marshall, cited infra, if anyone ever provided a remedial effect for a disease by following the teachings of Kawai et al., it was an unrecognized accident, since Kawai et al. does not teach or suggest that the sugar can extract can provide a remedial effect for any disease. Thus, under the reasoning of In re Marshall, the anticipation rejection over Kawai et al. should be withdrawn for this additional reason.

Accordingly, for these reasons, it is considered that claims 153 and 168, as amended, are clearly novel over Kawai et al. Claims 154-158, 160 and 163-167 all depend from claim 153 and thus are considered to be novel over Kawai et al. for at least the same reasons as given above for claim 153. Favorable consideration and withdrawal of the rejection of claims 153-158, 160, and 163-167 under 35 U.S.C. § 102(b), over Kawai et al., is requested. Claims 169-173, 175 and 178-182 all depend from claim 168 and thus are considered to be novel over Kawai et al. for at least the same reasons as given above for claim 168.

Claims 153-182 have been rejected under 35 U.S.C. §103(a) as being obvious over Kawai et al., in view of U.S. Patent No. 5,443,650 (Saska), U.S. Patent No. 5,788,812 (Agar et al.), U.S. Patent no. 5,454,952 (Brewer) and U.S. Patent no. 5,102,553 (Kearney). This rejection, at least insofar as it applies to claims 153 and 168, as amended, is respectfully traversed and reconsideration is requested for the reasons which follow.

Kawai et al. discloses a method wherein sugar cane extracts are administered to human or animal subjects, as seen from Examples 4-5, relied on by the Examiner, for the purpose of providing a deodorizing effect. The sugar cane extract can be used in foods, feeds, and medicines.

Saska discloses a method for softening an aqueous sugar juice for improved recovery of the sugars contained in the juice. A strong cation exchange resin is used for the softening and resultant improved recovery of sugars, as seen in column 2, lines 21-33.

Agar et al. discloses a method for the recovery of lignin and by-products from pulping of fibrous material, as seen in column 2, lines 66-67. More specifically, Agar et al. discloses a method for obtaining a novel lignin, a novel low molecular weight lignin, and purified furfural, as discussed in column 3, lines 22-41. The fibrous plant materials are preheated with low-pressure steam, and contacted with the twice-employed mixture of 60% ethanol and 40% water, as mentioned by the Examiner. The resulting extract or "black liquor" contains lignin, hemicellulose, other saccharides and extractives, as discussed in column 4, lines 24-45 of Saska.

Brewer discloses a method for at least partially removing inorganic ions from a sugar solution containing the ions, as can be seen from column 3, lines 31-34. For this purpose, Brewer employs an ion exchange process using strongly acidic ion exchange resins or cation exchange resins in their sodium form, as well as electrodialysis, as mentioned by the Examiner.

Kearney discloses simulated moving bed technology with ion exchange resins in column 1, lines 30-51, as mentioned by the Examiner. However, this technique is employed for the separation of sucrose from sugar cane.

The present invention, as claimed in amended claims 153 and 168, is clearly novel over Kawai et al. as discussed above, since amended claims 153 and 168 now require administration of a sugar cane extract to a human or animal to provide a remedial effect to a human or animal <u>infected</u> with a bacterial or a fungal infection. Kawai et al. contains no teaching or suggestion to administer a sugar cane extract to an infected or diseased human or animal to provide a remedial effect, as discussed above, nor would a skilled person be led to administer a sugar cane extract to an infected or diseased human or animal by the teachings of Kawai et al. since Kawai et al. does not teach or suggest any beneficial effect of such administration which is related to the treatment of a disease caused by an infection.

None of Saska, Agar et al., Brewer or Kearney teaches or suggests the administration of a sugar cane extract to a human or animal now require administration of a sugar cane extract to a human or animal to provide a remedial effect to a human or animal <u>infected</u> with a bacterial or a fungal infection. Also, none of Saska, Agar et al., Brewer or Kearney teaches or suggests any beneficial effect related to a remediation effect in the treatment of a disease caused by an

infection. Thus, there is also no motivation in any of Kawai et al., Saska, Agar et al., Brewer or Kearney to administer a sugar cane extract to an infected or diseased human or animal, nor is there any disclosure in these references that would provide a skilled person with an expectation of successful remediation effect in the treatment of a disease caused by an infection by such administration.

In view of the foregoing, Applicant respectfully submits that the Official Action does not set forth a *prima facie* case of obviousness in support of the rejection under 35 U.S.C. § 103(a). According to M.P.E.P. § 2143,

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. **Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.**
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. [*Citation omitted.*] (emphasis added)

In the present case, none of the references teach the element of claim 153, as amended, of administering a sugar cane-derived extract to a human or animal that has been infected by a disease for the purpose of providing a remedial effect on said disease. Accordingly, for these reasons, it is considered that claim 153, as amended, is clearly unobvious over Kawai et al., taken in combination with Saska, Agar et al., Brewer and Kearney. Claims 154-167 all depend from claim 153 and thus are considered to be unobvious over Kawai et al., taken in combination with Saska, Agar et al., Brewer and Kearney for at least the same reasons as given above for claim 153. Favorable consideration and withdrawal of the rejection of claims 153-167 over Kawai et al. taken in combination with Saska, Agar et al., Brewer and Kearney, is requested.

Similarly, claim 168 is clearly unobvious over Kawai et al. taken in combination with Saska, Agar et al., Brewer and Kearney since claim 168 also requires administration of a sugar cane-derived extract to a human or animal that has been infected by a disease to provide a remedial effect on said disease. None of Kawai et al., Saska, Agar et al. Brewer or Kearney teaches or suggests this limitation of claim 168. Claims 169-183 all depend from claim 168 and

thus are considered to be unobvious over Kawai et al., taken in combination with Saska, Agar et al., Brewer and Kearney for at least the same reasons as given above for claim 168. Favorable consideration and withdrawal of the rejection of claims 169-183 over Kawai et al. taken in combination with Saska, Agar et al., Brewer and Kearney, is requested.

Along with this response, the applicant has provided a full-text translation of JP57-106624 for consideration by the Examiner. JP57-106624 discloses that an extract of bagasse provides an anti-viral effect. However, JP57-106624 does not disclose that the extract of bagasse may be used as an anti-bacterial or anti-fungal agent. It is common general knowledge in the art that an agent that is effective against a virus is not necessarily effective against bacteria or fungi. Accordingly, the subject matter of claims 153-182 is considered to be novel and unobvious over JP57-106624 for at least this reason.

With regard to claims 183-204, the sugar cane-derived extract has been limited to a sugar-cane derived extract comprising a component having a molecular weight of less than 1,000 as an active ingredient, based on example 2 of the present application, as originally filed. JP57-106624 discloses that fractions A to C are obtained by Sephadex™ G-25 column chromatography, and that only fraction A has anti-viral activity. In addition, only fractions 1 and 3, of fractions 1-4 contained in fraction A, are said to have anti-viral activity. Fraction 1 of JP57-106624 contains polysaccharides having a molecular weight of 10,000 to 50,000 and fraction 3 of JP57-106624 contains polyphenols with molecular weights of 50,000 to 100,000. Thus, JP57-106624 teaches away from the subject matter of claims 183-204, since the skilled person would expect from JP57-106624 that only components of bagasse having molecular weights in excess of 10,000 would have an anti-viral effect. Accordingly, the subject matter of claims 183-204 is considered to be novel and unobvious over JP57-106624 for at least this reason.

Favorable consideration, entry of the amendment and issuance of a Notice of Allowance are solicited. Should the Examiner have any questions she is encouraged to call the Applicant's representative listed below.

Respectfully submitted,

Dated: July 13, 2004

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Excerpts translations of JP57-106624

Title of the invention

Anti-Viral Agent

Claims

1. An anti-viral agent which comprises polysaccharides and water-soluble lignin, as active ingredients, obtained from Gramineus plants.

2. The anti-viral agent according to claim 1, characterized in that said Gramineus plant is bagasse.

(omitted.)

Example 1

Water was added in an amount of 5 liters per kg of bagasse, to which crude enzyme mentioned below was added in a concentration of 0.1 to 0.5 % and the pH was adjusted to a range of from 4.2 to 6.2. Then, the temperature was set to a range of from 35 to 45 C to allow the enzyme reaction to proceed in the range of said temperature for 8 to 24 hours, whereby polysaccharides and water-soluble lignin in bagasse were extracted in water. The mixture was then filtered through a filter cloth to remove residuals and further filtered through a filter to remove minute residuals.

Subsequently, this aqueous solution was deproteinized by 10 % TCA (trichloroacetic acid) or the like, and a large excess of 95 % ethanol was added. The resulting precipitate was separated by centrifugation and was then dried by freeze-drying or the like to obtain an anti-viral agent of this invention.

The aforesaid crude enzyme was obtained as follows.

That is, Basidiomycetes of , for instance, a shiitake mushroom were cultured in a liquid medium and a filtrate of the culture was subjected to salting-out by ammonium sulfate or the like, dialyzed, and freeze-dried. The crude enzyme contains cellulase, lignase, glucanase, chitinase and the like.

Further, the agent obtained above was subjected to isolation

and identification steps as follows.

That is, the freeze-dried powder obtained above was dissolved in a small amount of water, and subjected to Sephadex G-25 column chromatography. 35 % ethanol was used as a solvent.

The results are as shown in Fig. 1. Anti-viral activity was observed only in fraction A according to a bio-assay.

Then, Fraction A was dissolved in a small amount of water, and subjected to DEAE cellulose column chromatography. Elution was performed in a step wise method with a pH 9.5 carbonate buffer and NaCl. The results are as shown in Fig. 2. The anti-viral activity was observed only in fractions 1 and 3 according to the bio-assay.

Then, it was confirmed by experiments that the substance of fraction 1 obtained above was polysaccharides with a molecular weight of 10,000 to 50,000 which showed no characteristic ultraviolet ray absorption, but a positive molisch reaction, a positive phenol-sulfuric acid reaction, and a negative ninhydrin reaction.

Further, it was confirmed by experiments that the substance of fraction 2 (this should have been fraction 3: comment in translation) was water-soluble polyphenol (water-soluble lignin) with a molecular weight of 50,000 to 100,000 which showed a positive phenol-sulfuric acid reaction, and a positive MAULE reaction.

The results above confirm that the active ingredients in the agent of this invention are polysaccharides and water-soluble lignin.

(Experiments 1, 2 and 3 omitted.)

Example 2

Water was added in an amount of 5 liters per kg of bagasse and heated to boil at 100 C for 3 to 10 hrs., whereby polysaccharides and water-soluble lignin in the bagasse were extracted in water. The mixture was then filtered through a filter cloth and the filtrate was subjected to centrifugation

to remove residuals and obtain an extract liquid.

Then, this extract liquid was subjected to isolation and identification steps as described above. It was confirmed that polysaccharides and water-soluble lignin were contained in the extract liquid.

Further, the extract liquid obtained above was used in anti-viral experiment as in Example 1. An excellent anti-virus effect was confirmed.

(Example 3 omitted.)

Fig. 1

Fig. 1 illustrates fractions by Sephadex G-25 chromatography of the extract liquid.

Fig.2

Fig. 2 illustrates fractions by DEAE cellulose column chromatography of fraction A of Figure 1.

Translations of JP57-106624

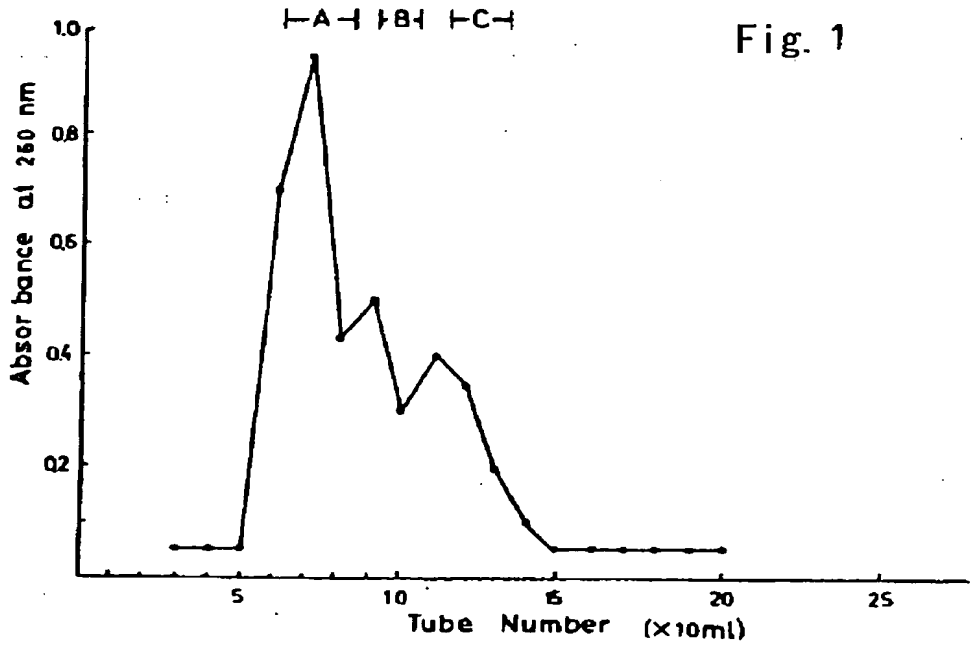

Fig. 1

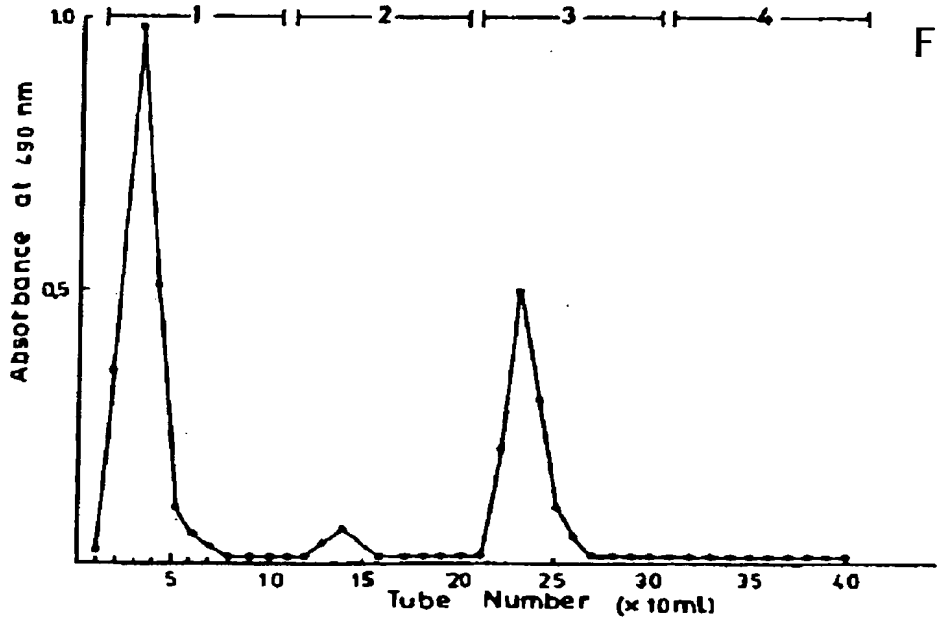

Fig. 2

IN THE MATTER OF THE APPLICATION OF EDWARD M. MARSHALL

Appeal No. 77-625.

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

578 F.2d 301; 1978 CCPA LEXIS 270; 198 U.S.P.Q. (BNA) 344

June 30, 1978, Decided

PRIOR HISTORY: [**1]

Serial No. 468,552.

CASE SUMMARY:

PROCEDURAL POSTURE: Patent applicant appealed from the decision of the Patent and Trademark Office Board of Appeals which rejected applicant's claims on grounds of anticipation, *35 U.S.C.S. § 102,* and obviousness, *35 U.S.C.S. § 103.*

OVERVIEW: The Patent and Trademark Office Board of Appeals sustained the examiner's rejection of patent applicant's claims for a patent describing use of certain drugs in a weight loss program. Applicant appealed and the court reversed, saying that the applicant's claims were neither anticipated or obvious under the prior art. The court said that rejection based on anticipation required all material elements of a claim to be disclosed in a single piece of prior art. It was improper to combine the teachings of multiple existing works to support a finding of anticipation. As to obviousness, the court said that although the function of the drugs described was known, it had never been described as being useful for weight loss and so was not obvious. Applicant's use actually took advantage of what was thought to be a disadvantage of the drug.

OUTCOME: The court reversed the rejection of applicant's patent claims on the grounds of anticipation because no single piece of prior art contained all the material elements of the claims, and on grounds of obviousness because the claims described a new and unanticipated use for an existing drug.

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Novelty & Anticipation

[HN1] Rejections under *35 U.S.C.S. § 102* are proper only when the claimed subject matter is identically disclosed or described in the prior art. In other words, to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art.

Patent Law > Novelty & Anticipation

[HN2] An accidental or unwitting duplication of an invention cannot constitute an anticipation.

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN3] Known disadvantages of a drug which would naturally discourage the search for new uses of that drug may be taken into account in determining obviousness.

COUNSEL:

Edward D. O'Brian, attorney of record, for appellant.

Joseph F. Nakamura for the Commissioner of Patents, *Kack E. Armore,* of counsel.

OPINIONBY:

LANE

OPINION: [*302]

Before MARKEY, Chief Judge, RICH, BALDWIN, LANE, and MILLER, Associate Judges.

LANE, Judge.

This is an appeal from the decision of the Patent and Trademark Office (PTO) Board of Appeals (board) sustaining the examiner's rejection under *35 USC 102* of claims 1-4 and entering a new ground of rejection under *37 CFR 1.196(b)* of claims 5-9 under *35 USC 103*. We reverse both rejections.

BACKGROUND

Invention

Normally, when food passes through the terminal region of the stomach, nerve endings there stimulate the release of two hormones, secretin and pancreozymin. These hormones then trigger the production and release of pancreatic enzymes necessary for digestion in the small intestine.

Applicant's weight control process involves anesthetizing these nerve endings with an orally administered anesthetic containing 50-2,000 mg of oxethazaine. This prevents the release of secretin and pancreozymin which in turn interferes with the production and release of the pancreatic enzymes. [**2] Thus, food passing through the small intestine is not digested and does not contribute calories to the body.

The following claims are before us on appeal:

1. In a weight control process in which a quantity of food is consumed and passes through the gastro intestinal digestive tract of a living body the improvement which comprises:

said quantity of food including foodstuffs requiring digestion caused by pancreatic enzymes for absorption into the bloodstream from the small intestine,

periodically anesthesizing [sic] the nerve endings in the digestive tract which release hormones when contacted by food passing through the digestive tract so as to trigger the release of said pancreatic enzymes into the digestive tract by the pancreas prior to said quantity of food contacting said nerve endings only prior to the passage of food into said digestive tract, said anesthetization being carried out to an extent effective and at a time effective to inhibit said nerve endings from releasing sufficient hormones to cause the release of said pancreatic enzymes which will contact said food as it passes through the digestive tract,

said anesthetization serving to prevent the release of [**3] said hormones when said nerve endings are contacted by said quantity of food, this having the effect of preventing release of said enzymes by the pancreas to the digestive tract so that said food passes through the digestive tract without being digested so that it is [sic not] capable of being absorbed into the bloodstream as a consequence of the absence of said enzymes.

2. A weight control process as claimed in claim 1 wherein:

said nerve endings are anesthesized [sic] by orally taking a quantity effective to cause said inhibition of an anesthetic means coated with a coating means which is effective to delay the release of said anesthetic means until said anesthetic means reaches the vicinity of said nerve endings in the digestive tract.

3. A weight control process as claimed in claim 2 wherein:

said anesthetic means is oexthazaine.

4. A weight control process as claimed in claim 2 wherein:

said anesthetic means is orally taken with an adherence means for causing said anesthetic means to adhere to the interior of the digestive tract.

5. A weight control process as claimed in claim 4 wherein:

said adherence means is albumin and is admixed with said anesthetic [**4] means, said anesthetic means and said albumin both being coated with said coating means. [*303]

6. A weight control process as claimed in claim 2 wherein:

from about 50 to about 2,000 milligrams of said anesthetic means are taken at one time, said time being prior to food being taken into the digestive tract.

7. A weight control process as claimed in claim 2 wherein:

from about 200 to about 800 milligrams of said anesthetic means are taken at one time, said time being prior to food being taken into the digestive tract.

8. A weight control process as claimed in claim 1 wherein:

said nerve endings are anesthesized [sic] by orally taking a quantity effective to cause said inhibition of an anesthetic means coated with a coating which will delay

the release of said anesthetic means until said anesthetic means reaches the vicinity of said nerve endings in the digestive tract,

said anesthetic means is oxethazaine, and from about 50 to about 2,000 milligrams of said anesthetic means are taken at one time, said time being prior to food being taken into the digestive tract.

9. A weight control process as claimed in claim 8 wherein:

said anesthetic means is orally [**5] taken with adherence means for causing said anesthetic [sic means] to adhere to the interior of the digestive tract, and

said adherence means is albumin and is admixed with said anesthetic [sic means], said anesthetic [sic means] and said albumin both being coated with said coating.

Prior Art

The references relied upon are: the PHYSICIAN'S DESK REFERENCE 1522-23 (25th ed. 1971) (PDR); and J. Slayback, E. Swena, J. Thomas, L. Smith, The Pancreatic Secretory Response to Topical Anesthetic Block of the Small Bowel, 61 SURGERY 591 (1967) (Slayback).

The PDR describes drugs containing the anesthetic eo oxethazaine for the treatment of esophagitis, gastritis, peptic ulcer and irritable colon syndrome. The recommended adult oral dose of these drugs is one or two teaspoons (10-20 mg oxethazaine) four times daily, fifteen minutes before meals and at bedtime. The PDR expressly warns against exceeding the recommended dosage. Regarding the use of these drugs in the treatment of peptic ulcer, the PDR explains that topical application of this local anesthetic inhibits the release of the acid-stimulating hormone, gastrin.

Slayback is an article reporting an investigation into [**6] the mechanism responsible for the release of the pancreatic secretory hormones, secretin and pancreozymin. Researchers found that application of the anesthetic oxethazaine HCL to isolated segments of the small intestine of surgically altered dogs caused a substantial reduction in the release of both secreting and pancreozymin. These results were consistent with the hypothesis that secretin and pancreozymin release is controlled by a local neural mechanism similar to the one which had been shown to control the release of the gastric secretory hormone, gastrin.

Proceedings Below

The examiner rejected claims 1-4 under *35 USC 102* as anticipated by the PDR and also rejected claims 1-9 under *35 USC 102*/103 as anticipated or obvious over a patent to Pober. n1/ The board affirmed the 102 rejection of claims 1-4 but reversed the 102/103 rejection of claims 1-9 and entered a new ground of rejection under *37 CFR 1.196(b)* rejecting claims 5-9 under *35 USC 103* as obvious in view of the combined teachings of PDR and Slayback. n2/

n1/ U.S. patent No. *3,740,440*, issued June 19, 1973, for "Method of Inhibiting Appetite for Food."

n2/ The board does not explain why this new ground of rejection was not applied to claims 1-4 as well. [**7] [*304]

OPINION

102 Rejection

[HN1] Rejections under *35 USC 102* are proper only when the claimed subject matter is identically disclosed or described in the prior art. *In re Arkley, 59 CCPA 804, 807, 455 F.2d 586, 587, 172 USPQ 524, 526 (1972).* In other words, to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. *Soundscriber Corp. v. United States, 360 F.2d 954, 960, 148 USPQ 298, 301 (Ct.Cl. 1966).* This basic principal of patent law has not been disturbed by our recent decision, *In re Samour, 571 F.2d 559, 197 USPQ 1 (CCPA 1978),* in which we affirmed a § 102(b) rejection of claims to a chemical compound based on a primary reference which disclosed the compound and additional references which established that a method of preparing the compound would have been obvious to one skilled in the art. In Samour, every material element of the claimed subject matter, the chemical compound, could be found in the primary reference, a disclosure of that compound.

Applying this rule of law to the present case, we must reverse the board's rejection of claims 1-4 under *35 USC 102* since the primary reference, the PDR, does not disclose [**8] every material element of the claimed subject matter. These claims are directed to a weight control process. Applicant uses an effective amount of the anesthetic, oxethazaine, to inhibit release of the pancreatic secretory hormones, secretin and pancreozymin, in order to control weight. The PDR, however, teaches using drugs containing the anesthetic oxethazaine to inhibit release of the acid-stimulating hormone, gastrin, in order to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome. Nothing in the PDR remotely suggests taking oxethazaine to lose weight. If anyone ever lost weight by following the PDR teachings it was an unrecognized accident. [HN2] An accidental or unwitting duplication of an invention

cannot constitute an anticipation. *In re Felton, 484 F.2d 495, 500, 179 USPQ 295, 298 (CCPA 1973).*

103 Rejection

The board seems to have combined: (1) the teaching of the PDR that oral administration of oxethazaine inhibits release of gastrin, (2) the teaching of Slayback that secretin and pancreozymin release is controlled by a local neural mechanism similar to the one which controls release of gastrin, and (3) the art-recognized fact that secretin and pancreozymin [**9] control the production and release of pancreatic enzymes necessary for digestion in the small intestine, to conclude that applicant's method of controlling weight by anesthetizing the nerve endings that stimulate the release of secretin and pancreozymin would have been obvious.

The problem with this rejection is that nowhere in any reference is there any suggestion to control weight by turning off the production and release of pancreatic enzymes. Although it has long been known that pancreatic enzymes are involved in digestion, from this record it appears that applicant is the first to suggest controlling weight by decreasing the quantity of pancreatic enzymes in the small intestine. To say this would have been obvious is to resort to impermissible hindsight.

Moreover, the PDR appears to teach away from using effective amounts of the anesthetic oxethazaine since it expressly cautions against exceeding the recommended does of 10-20 mg. This would not be an effective amount for controlling weight by appellant's process. Although Slayback, which discusses tests conducted solely on dogs, recognizes that higher concentrations of oxethazaine will produce "complete absence of stimulation [**10] of hormonal release," this does not negate the PDR warning with respect to the oral administration to humans. [HN3] Known disadvantages of a drug which would naturally discourage the search for new uses of that drug may be taken into account in determining obviousness. See *United States v. Adams, 383 U.S. 39, 52 (1966).* [*305]

Accordingly, for the reasons set forth herein, the decision of the board is reversed. n3/

n3/ The board rejected only claims 5-9 under *35 USC 103.* In the interest of judicial economy, we note that our reversal of that rejection is not based on any limitations of claims 5-9 not found in broader claims 1-4 as well.

REVERSED

DISSENTBY:

MARKEY (In Part)

DISSENT:

MARKEY, Chief Judge, dissenting-in-part, with whom BALDWIN, J., joins.

Though I wholeheartedly agree with the majority's treatment of the § 102 issue, I respectfully dissent from the majority's conclusion of non-obviousness under § 103.

The majority agrees that the board considered "the art recognized fact that secretin and pancreozymin control the production and release of pancreatic enzymes necessary for digestion in the small intestine." Nowhere in the record is there any dispute on that point. [**11] Moreover, the majority also recognizes that "it has long been known that pancreatic enzymes are involved in digestion."

Appellant and all others having ordinary skill in the art knew that pancreatic enzymes play a major role in the digestion of food. If food is not digested, it is excreted without being absorbed into the body. If food is not absorbed, the body cannot gain weight. It follows, therefore, that decreasing pancreatic enzyme quantity (or eliminating it altogether) must decrease weight. The particular compound chosen by appellant to shut off or decrease the flow of pancreatic enzymes was known in the art and used for that purpose.